OCT 1 4 2003

K033185

510(k) Summary - COBAS Integra ALP IFCC Gen.2

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: September 29, 2003
Device Name	Proprietary name: Roche Diagnostics COBAS Integra ALP IFCC Gen.2 Common name: Alkaline phosphatase Assay Classification name: Alkaline phosphatase or isoenzymes test system
Device description	The COBAS Integra ALP IFCC Gen.2 is a colorimetric assay for the determination of the catalytic activity of alkaline phosphatase in serum or plasma in accordance to the recommended reference method of the International Federation of Clinical Chemists (IFCC). In the presence of magnesium and zinc ions, p-nitrophenyl phosphate is cleaved by phosphatases into phosphate and p-nitro-phenol. The p-nitro-phenol released is directly proportional to the catalytic ALP activity.
Intended use	The cassettes COBAS Integra ALP IFCC Gen.2 Small (ALP2S) and COBAS Integra ALP IFCC Gen.2 Large (ALP2L) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the catalytic activity of alkaline phosphatase in human serum and plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

510(k) Summary - COBAS Integra ALP IFCC Gen.2, continued

Predicate Device

We claim substantial equivalence to the currently marketed COBAS Integra ALP IFCC Assay. (K981897).

Reagent Summary

The following table describes the similarities and differences between the COBAS Integra ALP IFCC Gen.2 and the predicate device.

Topic	COBAS Integra ALP IFCC (K981897)	COBAS Integra ALP IFCC Gen.2 (Modified Device)
Intended Use	The cassettes COBAS Integra ALP IFCC (ALPL2 and ALPL6) contain an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the catalytic activity of alkaline phosphatase in serum and plasma.	The cassettes COBAS Integra ALP IFCC Gen.2 Small (ALP2S) and COBAS Integra ALP IFCC Gen.2 Large (ALP2L) contain an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the catalytic activity of alkaline phosphatase in serum and plasma.
Method	colorimetric assay in accordance with the recommended reference method of the International Federation of Clinical Chemistry (IFCC)	Same
Sample type	Serum Heparin plasma	Same
Measuring range	2 - 1500 U/L	2 - 1200 U/L
Expected values	Measured at 37° C *Adults* Females: 35 - 104 U/L Males: 40 - 129 U/L *Children* 1 day: < 250 U/L 2 - 5 days: < 231 U/L 6 days - 6 months: < 449 U/L 7 months - 1 year: < 462 U/L 1 - 3 years: < 281 U/L 4 - 6 years: < 269 U/L 7 - 12 years: < 300 U/L 13 - 17 years (f): < 187 U/L 13 - 17 years (m): < 390 U/L	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 4 2003

Ms. Sherri L. Coenen
Regulatory Affairs Consultant
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k033185
Trade/Device Name: COBAS Integra ALP IFCC Gen.2
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE
Dated: September 29, 2003
Received: October 1, 2003

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K033185

Device Name: COBAS Integra ALP IFCC Gen.2

Indications For Use:

The cassettes COBAS Integra ALP IFCC Gen.2 Small (ALP2S) and COBAS Integra ALP IFCC Gen.2 Large (ALP2L) contain an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the catalytic activity of alkaline phosphatase in human serum and plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

Carol C. Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)